REMARKS

Status of Claims

Claims 1-9, 12, 14-27, 30-34, and 50-58 were previously pending.

Upon entry of this paper, claims 1, 3, 7, 16, 32-34, 50-52, 54, and 58 are amended, claims 12, 15, 27, 30-31, and 33 are canceled, and new claims 59-61 are added. Applicants reserve the right to pursue any canceled subject matter in one or more continuing applications.

Claims 1-9, 14, 16-26, 32, 34, and 50-61 are now pending.

Support for Amendments

Claims 1, 32, 34, and 52 are amended to change "gelatine" to "gelatin" as suggested by the Examiner. Support can be found in the specification as filed.

Claims 1, 32, and new claim 59 are amended to include "hyaluronic acid." Support can be found in the specification as filed, for example at page 10, lines 1-2.

Claims 1, 32, and 34 are amended to include the term "haemostatic" and "dry." Support can be found in the specification as filed, for example at page 1, lines 6-13.

Claims 3 and 54 are amended to change "elongate" to "elongated" as suggested by the Examiner. Support can be found in the specification as filed, for example at page 17, lines 36-39.

Claims 7 and 58 are amended to remove "such as by finger pressure" from the claims. New claims 60 and 61 are directed to "finger pressure." Support for the new claims can be found in previous claims 7 and 58, and the specification as filed, for example at page 20, lines 23-35.

Claims 16, 50, and 52 are amended to change dependency. Support can be found in the specification as filed.

Claim 51 is amended to remove the phrase "hyaluronic acid" and the term "derivatives" from the claim. Support can be found in the specification as filed, for example at page 15, lines 8-13.

No new matter is introduced.

Restriction Requirement

Applicants thank the Examiner for the indication that the Restriction Requirement of February 20, 2009 is withdrawn and all pending claims are examined.

Information Disclosure Statements

Applicants previously submitted four Information Disclosure Statements (February 15, 2008, September 3, 2008, February 9, 2009, and May 27, 2009).

The September 3, 2008 and February 9, 2009 Information Disclosure Statements have been considered in full, as evidenced by the initialed copies of the forms PTO/SB08 returned by the Examiner.

With regard to the February 15, 2008 IDS, copies of some of the cited references are allegedly missing from the USPTO Image File Wrapper, and as such only the US patents and published applications have been considered to date, as evidenced by the initialed copies of the forms PTO/SB08 returned by the Examiner. Applicants respectfully note that the missing references were submitted on a CD-ROM on February 15, 2008, as evidenced by the Certificate of Express Mailing of record for the date, and that if the references are missing from the USPTO Image File Wrapper, the problem may have been due to USPTO processing. However, in order to advance prosecution, Applicants re-submit herewith additional copies of the missing references. Applicants respectfully request consideration of the references as indicated by return of an initialed copy of the form PTO/SB08.

Finally, Applicants note that the May 27, 2009 IDS was filed two days before the May 29, 2009 Office Action and has not yet been considered. An updated Form SB08 is submitted herewith. Applicants respectfully suggest that no additional fees should be required as the references were filed prior to the mailing of a first Office Action. However, if a fee is required for consideration, the Commissioner is hereby authorized to charge any fees which may be required for consideration, or credit any overpayment to Deposit Account No. 50-3732, Order No. 13323.105002.

Claim Objections

The Office Action objects to claims 1, 12, 27, 30, 31, 33-34, and 52, indicating that the term "gclatine" should be amended to "gelatin." Applicants respectfully traverse on the basis that "gclatine" is a recognized alternate spelling of gelatin. See, for example, the Merriam-Webster's Online Dictionary entry for gelatine. Applicants note the following guidance from the MPEP:

> Examiners should not object to the specification and/or claims in patent applications merely because applicants are using British English spellings (e.g., colour) rather than American English spellings. It is not necessary to replace the British English spellings with the equivalent American English spellings in the U.S. patent applications. Note that 37 CFR 1.52(b)(1)(ii) only requires the application to be in the English language. There is no additional requirement that the English must be American English.

(MPEP 608.01). Applicants submit that the objection to the spelling of "gelatine" is not consistent with USPTO policy as set forth in the MPEP. However, in order to advance prosecution, the claims are amended as suggested.

The Office Action objects to claim 32, suggesting that the phrase "according to" or "as defined in" should be inserted. However, the objection is moot because claim 32 is canceled.

Applicants respectfully request withdrawal of the objections.

Claim Rejections

35 U.S.C. § 112, second paragraph

The Office Action rejects claims 3, 7, 15-17, 33, 51, 54, and 58 under 35 U.S.C. § 112, second paragraph, as failing to distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse.

The Office Action rejects the term "elongate" and suggests replacement with the term "elongated." Applicants note the following guidance from the MPEP:

> The examiner's focus during examination of claims for compliance

> with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available . . . Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

(MPEP 2173.02). Applicants submit that the term "elongate" meets the statutory requirement for clarity and precision and that "[s]ome latitude in the manner of expression and the aptness of terms should be permitted" as directed by the MPEP. However, the term is amended as suggested by the Examiner.

The phrase "such as by finger pressure" is rejected as being indefinite. The phrase is removed, and new claims 60 and 61 are added with the element of "finger pressure" without the "such as" language cited as the basis for the rejection.

The phrase "dry powder" is rejected because the Office Action takes the position that a powder is "generally assumed to be inherently dry with 0% moisture" (Office Action, p. 3, lines 17-19). Applicants respectfully traverse what appears to be an improper finding of "Official Notice" by the Examiner. According to the MPEP:

> Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in In re Ahlert, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing In re Knapp Monarch Co., 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

(MPEP 2144.03). In this case, the facts are **not** capable of instant and unquestionable demonstration as being well-known. To the contrary, some powders are known to absorb moisture from their surroundings, including ambient moisture from air. The amount of moisture a powder absorbs will depend on the chemical properties of the powder in question. Powders

that degrade upon exposure to moisture are often stored in desiccators, and powders that are not stored in desiccators may have greater than 0% moisture content depending on their mode of preparation and/or exposure to moisture in the air. The defining characteristic of a powder is not 0% moisture content, but rather fine particles that flow freely when shaken or tilted. See, for example, the Merriam-Webster's Online Dictionary entry for "powder." In fact, even snow (which is 100% water in solid form) can exist as a powder. Moreover, Silver (US Patent 5,196,185) is relied upon by the Office Action, and Silver describes "collagen powder in the form of discrete particles" (col. 2, lines 36-38), where particulate collagen "absorbs 10 to 50 times its weight of water," (col. 2, lines 41-42). It follows that the collagen powder as taught by Silver is not inherently a 0% moisture powder, and as such, the prior art does not support the Examiner's position that powders inherently have 0% moisture. Furthermore, the instant application provides detailed guidance to one of ordinary skill in the art at page 8, lines 27-37 with regard to the Applicants' intended moisture content according to the invention. As such, the term "dry" is sufficiently clear and precise.

In view of the above, Applicants respectfully request withdrawal of the rejection, keeping in mind the MPEP's guidance with respect to the Examiner's burden in maintaining an assertion of Official Notice following Applicants' traversal:

> If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2).

(MPEP 2144.03).

The phrase "poured density" is rejected by the Examiner as being potentially the same as "density." Applicants respectfully point out that "poured density" is a term of the art. See, for example, Santomaso et al. ("Powder flowability and density ratios: the impact of granules packing," Chemical Engineering Science, vol. 58, pp. 2857-2874, 2003) which describes

"poured density" as one method of measuring density according to industry standards:

> *Poured density* is perhaps the most widely used so that it is frequently referred as *apparent density* without further specification. Accordingly, it is the subject of standard procedures (ISO 3923-1 (International Organization for Standardization, 1976) or equivalently ASTM B212 (American Society for Testing and Materials, 1999a), ASTM B417 (American Society for Testing and Materials, 1989), and EN 23923-1 (European Committee for Standardization, 1993a)).

(Santomaso, 2858, column 1). As the phrase "poured density" is a term of art as evidenced by Santomaso, the phrase clearly meets the statutory requirements for clarity and definiteness.

The Office Action rejects claim 33 for lacking an active step in the method as claimed. The rejection is moot in view of the cancellation of claim 33.

The Office Action rejects claim 51 for the term "derivatives." The rejection is moot in view of the amendment to claim 51.

Applicants respectfully request withdrawal of the rejections for the reasons as discussed above.

35 U.S.C. § 102(b)

The Office Action rejects claims 30-33 under 35 U.S.C. § 102(b) as being anticipated by Silver (US Patent No. 5,196,185). Applicants respectfully traverse, and note that the following comments are directed to claim 32, as the cancellation of claims 30-31 and 33 renders the rejection of those claims moot.

Claim 32 is directed to a method for promoting haemostasis in a patient in need thereof, said method comprising spraying a haemostatic powder composition comprising gelatin and hyaluronic acid, said composition having a mean particle size in the range of 30-250 μm, wherein said powder is dry, onto at least a portion of an area where bleeding occurs. In contrast, Silver is directed to particulate collagen compositions and is silent with respect to haemostatic powder compositions comprising gelatin and hyaluronic acid. In fact, the only mention of gelatin in Silver is with respect to formation of a gel carrier, which would not be a powder composition as claimed (see Silver, col. 3, lines 23-24). Moreover, the particulate collagen of

Silver is mixed with a low molecular weight alcohol at a collagen to liquid ratio of 1:5 to 1:50 to form a collagen dispersion (see Silver, col. 2, lines 49 to 53 and lines 60 to 63). Thus, the composition of Silver is not dry as it contains from 80 to 98% liquid and from 2 to 20% collagen.

In describing the legal standard for anticipation, the Federal Circuit has held that "[a]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). As Silver fails to describe exactly what is claimed in claim 32, Applicants respectfully request withdrawal of the rejection.

35 U.S.C. § 103(a)

The Office Action rejects claims 1-9, 12, 14-22, 25-27, 34, and 50-58 under 35 U.S.C. § 103(a) as being unpatentable in view of Ferdman (US Patent No. 5,951,531) combined with Silver (US Patent No. 5,196,185).

Dependent claims 23-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Ferdman (US Patent No. 5,951,531) combined with Silver (US Patent No. 5,196,185) in view of Epstein (US Patent No. 6,045,570).

Claims 1-9, 14, 16-26, 50-51, and 60

Applicants respectfully traverse the rejection of claims 1-9, 14, 16-26, 50-51, and 60 for at least the reason that the cited references, either alone or in combination, fail to teach or suggest all of the claimed elements.

Claim 1 is directed to a powder delivery system containing a chamber storing a haemostatic composition comprising dry gelatin powder and hyaluronic acid, said composition having a mean particle size in the range of 30-250 μm, said chamber having at least one discharge opening sized for distributing said composition. Dependent claims 2-9, 14, 16-26, 50-

51, and 60 include at least all of the features of claim 1. Independent claim 32[1] is directed to a method for promoting haemostasis in a patient in need thereof, said method comprising spraying a haemostatic powder composition comprising gelatin and hyaluronic acid, said composition having a mean particle size in the range of 30-250 μm, wherein said powder is dry, onto at least a portion of an area where bleeding occurs. All of the above claims require a dry powder comprising gelatin and hyaluronic acid in a particle size in the range of 30-250 μm.

Ferdman teaches an apparatus and a method for applying a particulate haemostatic agent, said apparatus comprising a haemostatic agent and a continuous gas source. The gas and the haemostatic agent are mixed in the apparatus and sprayed onto living tissue. Ferdman does not disclose a particle size for the haemostatic composition, or the incorporation of hyaluronic acid into the composition to be sprayed.

Silver teaches compositions of particulate collagen for use in wound dressings with a range of particle sizes. Silver does not teach gelatin in powdered compositions, but rather teaches the use of gelatin as a carrier in gel form. See col. 3, lines 19-25. Moreover, Silver teaches that the particulate collagen is mixed with a low molecular weight alcohol at a collagen to liquid ratio of 1:5 to 1:50 to form a collagen dispersion (see col. 2, lines 49 to 53 and lines 60 to 63). Thus, the composition of Silver is not dry as it contains from 80 to 98% liquid and from 2 to 20% collagen. Moreover, Silver fails to teach compositions of a haemostatic powder comprising gelatin and hyaluronic acid.

As neither Ferdman nor Silver teach compositions of haemostatic powder comprising gelatin and hyaluronic acid, one of ordinary skill in the art looking at the combination of Ferdman and Silver would have no way of arriving at the presently claimed elements which require at least a dry powder comprising gelatin and hyaluronic acid in a particle size in the range of 30-250 μm.

With regard to dependent claims 23-24, the Office Action relies on the teachings of Epstein with respect to thrombin as an agent to be mixed with collagen powder in order to form a

[1] Independent claim 32 is not rejected under 35 USC 103(a). However, to the extent that the USPTO may attempt to apply the cited references against claim 32 in the future, the claim is included in the discussion of the present rejection.

biological sealant composition. See Office Action, p. 9, lines 8-9. However, Epstein fails to remedy the deficiencies of Ferdman and Silver with respect to a dry powder comprising gelatin and hyaluronic acid in a particle size in the range of 30-250 μm.

For at least the reasons discussed above, the cited references fail to render the instant claims obvious. Applicants respectfully request withdrawal of the rejection.

Claims 34, 52-59, and 61

Independent claim 34 is directed to a powder delivery system containing a chamber for storing a dry haemostatic powder composition comprising gelatin or collagen powder having a mean particle size in the range of 30-250 μm, said chamber comprising at least one discharge opening sized for distributing said composition and a protective structure being a skirt portion arranged to extend from the discharge opening. Dependent claims 52-59 and 61 include at least all of the features of claim 34. All of the above claims require at least a dry powder comprising gelatin or collagen in a particle size in the range of 30-250 μm and a powder delivery system comprising a protective structure with a skirt portion. Applicants respectfully traverse the rejection for at least the reason that neither Ferdman nor Silver teach a protective structure in the form of a skirt portion.

The Examiner relies on Ferdman (col. 5, lines 50-55) for a teaching of a sliding valve gate, and argues that the structure of Ferdman is a protective structure equivalent to a skirt portion extending from the discharge opening, as both structures function to control the discharge of the haemostatic agent. However, the sliding valve gate disclosed by Ferdman is not equivalent to a protective structure as claimed. Rather, the sliding valve gate of Ferdman is used for operating the embodiment showed in Figure 5 to successively open or close gas inlets. See col. 5, lines 15-55 and Figure 4 ("110"). In Figure 4, the sliding valve gate 110 resembles a stick with a handle, and not a skirt portion arranged to extend from the discharge opening.

The instant specification describes the requirements for a skirt portion as claimed:

> A special distance protective structure is illustrated in Fig. 4. The embodiment shown comprises a ring (12) supported by legs (13), so the discharge opening (4) of the extended nozzle cannot abut a surface. Alternatively, the protective structure may be a skirt (not

shown) attached to the discharge opening (4), said skirt extending in front of the discharge opening (4) of the extended nozzle.

(Specification, page 21, lines 7-11). It follows from this description that a protective structure being a skirt portion is attached to and will extend in front of the discharge opening. A skirt will, as the word implies, refer to a tube- or cone-shaped structure. This is not taught or suggested by the elongated stick-like sliding valve gate of Ferdman. Silver fails to remedy the deficiency of Ferdman in that Silver is entirely silent with respect to a protective structure in the form of a skirt portion.

For at least the reasons discussed above, the cited references fail to render the instant claims obvious. Applicants respectfully request withdrawal of the rejection.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required for this paper, or credit any overpayment to Deposit Account No. **50-3732**, Order No. **13323.105002**. Furthermore, in the event that an extension of time is required, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-noted Deposit Account No. **50-3732** and Order No. **13323.105002**.

Respectfully submitted,
KING & SPALDING, L.L.P.

Dated: September 10, 2009

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